

Complete if Known

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet

1

of

2

Application Number

09/894,001 10/694,001

Filing Date

October 28, 2003

First Named Inventor

Bernward SCHÖLKENS

Art Unit

1614

Examiner Name

R. Henley, III.

Attorney Docket Number

02481.1707-01

U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS

Examiner Initials	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

Note: Submission of copies of U.S. Patents and published U.S. Patent Applications is not required.

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No. ¹	Foreign Patent Document Country Code ³ Number ⁴ Kind Code ⁶ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation ⁸

NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation
	1	Braunwald, Ed., "Heart Disease: A Textbook of Cardiovascular Medicine," vol. 1, Chapter 15, "Clinical Aspects of Heart Failure: High-Output Heart Failure; Pulmonary Edema," W.B. Saunders Company, pp. 445-470 (1997)	
	2	Pitt et al., "The QUinapril Ischemic Event Trial (QUIET): Evaluation of Chronic ACE Inhibitor Therapy in Patients With Ischemic Heart Disease and Preserved Left Ventricular Function," The American Journal of Cardiology, vol. 87, pp. 1058-1063 (2001)	
	3	Schulz et al., "Cardiovascular Therapy: Evidence-based Medicine -Questions and Answers-," Table of Contents and Chapter F, "Post-myocardial infarction with poor LV function," medpharm GmbH Scientific Publishers, pp. 7-14 and 171-183 (2001)	
	4	The EUROpean trial On reduction of cardiac events with Perindopril in stable coronary Artery disease Investigators, "Efficacy of perindopril in reduction of cardiovascular events among patients with stable coronary artery disease: randomised, double-blind, placebo-controlled, multicentre trial (the EUROPA study), The LANCET, vol. 362, pp. 782-788 (2003)	
	5	Abstract From the 65 th Scientific Sessions, Circulation, vol. 86 (4 Suppl. 1), p. I-53, Abstracts 0207-0210 (1992)	
	6	Anderson et al., "Therapeutic Advantage of Converting Enzyme Inhibitors in Arresting Progressive Renal Disease Associated with Systemic Hypertension in the Rat," J. Clin. Invest., vol. 77, pp. 1993-2000 (1986)	
	7	Brown et al., "Angiotensin-Converting Enzyme Inhibitors," Circulation, vol. 97, pp. 1411-1420 (1998)	
	8	Cambien et al., "Deletion polymorphism in the gene for angiotensin-converting enzyme is a potent risk factor for myocardial infarction," Nature, vol. 359, pp. 641-644 (1992)	
	9	Deng et al., "Proinflammatorische Zytokine und kardiale Pumpfunktion," Z. Kardiol, vol. 86, pp. 788-802 (1997)	Abstract
	10	FDA Orange Book Active Ingredient Detail Record Search, printed on June 8, 2001	
	11	Editorial, "Angiotensin II: Hemodynamic Regulator or Growth Factor?," J. Mol Cell Cardiol, vol. 22, pp. 739-747 (1990)	
	12	Law, "Lipids and cardiovascular disease," Evidence Based Cardiology, BMJ Books, pp. 191-205 (1998)	
	13	Lee et al., "Effects of perindopril on hypertension and stroke prevention in experimental animals," Can. J. Cardiol., vol. 10 (suppl. D), pp. 33D-36D (1994)	
	14	Ogiku et al., "Prophylactic Effect of Imidapril on Stroke in Stroke-Prone Spontaneously Hypertensive Rats," Stroke, vol. 24, no. 2, pp. 245-252 (1993)	

Rod Henley 4/19/06

[illegible]

Examiner Signature		Date Considered	4/19/04
-----------------------	---	--------------------	---------

4/19/04

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet

1

of

6

Complete if Known

Application Number 40/594,004

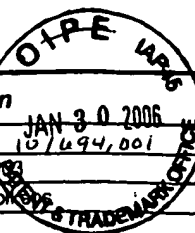
Filing Date October 28, 2003

First Named Inventor Bernward Schokops

Art Unit 1614

Examiner Name R. Henley

Attorney Docket Number 02481.1707-01



U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS

Examiner Initials	Cite No. ¹	Document Number	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
		3,983,140	28 Sept. 1976	Endo et al.	
		4,231,938	04 Nov. 1980	Monaghan et al.	
		4,346,227	24 Aug. 1982	Terahara et al.	
		4,444,784	24 April 1984	Hoffman et al.	
		4,448,784	15 May 1984	Glamkowski et al.	
		4,450,171	22 May 1984	Hoffman et al.	
		4,681,893	21 July 1987	Roth	
		4,722,810	02 Feb. 1988	Delaney et al.	
		4,739,073	19 April 1988	Kathawala	
		4,743,450	10 May 1988	Harris et al.	
		4,749,688	07 June 1988	Haslanger et al.	
		4,804,770	14 Feb. 1989	Karnewsky	
		4,857,520	15 Aug. 1989	Urbach et al.	
		5,223,516	29 June 1993	Delaney et al.	
		5,225,401	06 July 1993	Seymour	
		5,273,995	28 Dec. 1993	Roth	
		5,362,727	08 Nov. 1994	Robl	
		5,366,973	22 Nov. 1994	Flynn et al.	
		5,403,856	04 Apr. 1995	Henning et al.	
		5,430,145	04 July 1995	Flynn et al.	
		5,442,008	15 Aug 1995	Fulberth et al.	
		5,502,199	26 March 1996	Angerbauer et al.	
		5,504,080	02 April 1996	Karnewsky	
		5,525,723	11 June 1996	Robl	
		5,552,397	03 Sept. 1996	Karnewsky et al.	
		5,612,359	18 March 1997	Murugesan	
		5,679,671	21 Oct. 1997	Oinuma et al.	
		5,684,016	04 Nov. 1997	Henning et al.	
		5,733,558	31 Mar 1998	Breton et al.	
		5,744,496	28 Apr. 1998	Henning et al.	
		5,747,504	05 May 1998	Henning et al.	

Note: Submission of copies of U.S. Patents and published U.S. Patent Applications is not required.

Rud J. Hoge

4/19/06

IDS Form PTO/SB/08: Substitute for form 1449A/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Application Number	10/694,001
				Filing Date	October 28, 2003
				First Named Inventor	Bernward Scholkens
				Art Unit	1614
				Examiner Name	R. Henley
Sheet	2	of	6	Attorney Docket Number	02481.1707-01

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation ⁹
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
[Signature]		EP 0 158 927 B1	23 Oct. 1985	Henning et al.	X	
		EP 0 363 934 B1	18 April 1990	Chen et al.		
		CA 2 026 686	01 May 1991	Tschollar		
		EP 0 481 522 B1	22 April 1992	Flynn et al.		
		EP 0 534 396 B1	31 March 1993	Warshawsky et al.		
		EP 0 534 492 B1	31 March 1993	Warshawsky et al.		
		EP 0 671 172 A1	13 Sept. 1995	Oinuma et al.		
		EP 0 738 510 A2	23 Oct. 1996	Breton et al.		
		EP 0 317 878 B1	31 May 1999	Fülberth et al.		
		CA 2 382 387	08 March 2001	Schoelkens et al.		
		CA 2 382 549	08 March 2001	Schoelkens et al.		

NON PATENT LITERATURE DOCUMENTS					Translation
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			
[Signature]		Schunkert H., et al., "Pharmacokinetics of ramipril in hypertensive patients with renal insufficiency," Eur J Clin Pharmacol., 37(3): 249-56 (1989)			
		Bauer B. et al., "An open multicenter study to assess the long-term efficacy, tolerance, and safety of the oral angiotensin converting enzyme inhibitor ramipril in patients with mild to moderate essential hypertension," J Cardiovasc Pharmacol., 13(Suppl 3): S70-4 (1989)			
		Kindler J., et al., "Therapeutic efficacy and tolerance of ramipril in hypertensive patients with renal failure," J Cardiovasc Pharmacol., 13(Suppl 3): S55-8 (1989)			
		Becker R.H. et al., "Loop diuretics combined with an ACE inhibitor for treatment of hypertension: a study with furosemide, piretanide, and ramipril in spontaneously hypertensive rats," J Cardiovasc Pharmacol., 13(Suppl 3): S 35-9 (1989)			
		Heber M.E. et al., "First dose response and 24-hour antihypertensive efficacy of the new once-daily angiotensin converting enzyme inhibitor, ramipril," Am J Cardiol., 62(4):239-45 (1988)			
		Zabludowski J. et al., "A multi-centre comparative study between ramipril and enalapril in patients with mild to moderate essential hypertension," Curr Med Res Opin., 11(2): 93-106 (1988)			
		Kaneko Y. et al., "Effect of ramipril, a new angiotensin converting enzyme inhibitor, on diurnal variations of blood pressure in essential hypertension," Am J Cardiol., 59(10): 86D-91D (1987)			
		Tochikubo O. et al., "Effect of ramipril on 24-hour variability of blood pressure and heart rate in essential hypertension," Am J Cardiol., 59(10): 83D-85D (1987)			
		de Leeuw P.W. et al., "Short- and long-term effects of ramipril in hypertension," Am J Cardiol., 59(10): 79D-82D (1987)			
		Becker R.A. et al., "Ramipril: review of pharmacology," Am. J Cardiol., 59(10): 3D-11D (1987)			
		Predel H.G. et al., "Combined treatment of severe essential hypertension with the new angiotensin converting enzyme inhibitor ramipril," Am J Cardiol., 59(10): 143D-148D (1987)			

Rand H. H. 4/12/04

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

3



of

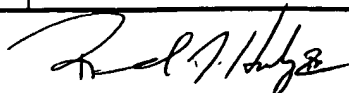
6

Complete if Known

Application Number	10/694,001
Filing Date	October 28, 2003
First Named Inventor	Bernward Scholkens
Art Unit	1614
Examiner Name	R. Henley
Attorney Docket Number	02481.1707-01

NON PATENT LITERATURE DOCUMENTS

	Walter U. et al., "Dose-response relation of the angiotensin converting enzyme inhibitor ramipril in mild to moderate essential hypertension," Am J Cardiol., 59(10): 125D-132D (1987)	
	Fukiyama K. et al., "Efficacy and safety of ramipril (HOE 498) in the treatment of hypertension: dose finding study," Am J Cardiol., 59(10):121D-124D (1987)	
	Karlberg B.E. et al., "Efficacy, tolerance and hormonal effects of a new oral angiotensin converting enzyme inhibitor, ramipril (HOE 498), in mild to moderate primary hypertension," Am J Cardiol., 59(10): 104D-109D (1987)	
	Stumpe K.O. et al., "Effects of the new angiotensin-converting enzyme inhibitor, ramipril, in patients with essential hypertension," Klin Wochenschr, 64(12): 558-62 (1986)	
	Bohm R.O. et al., "Studies on the antihypertensive effect of single doses of the angiotensin converting enzyme inhibitor ramipril (HOE 498) in man," Eur J Clin Pharmacol.; 30(5): 541-7 (1986)	
	de Leeuw P.W. et al., "Preliminary experiences with HOE 498, a novel long-acting converting enzyme inhibitor, in hypertensive patients," J Cardiovasc Pharmacol., 7(6): 1161-5 (1985)	
	Mordchai Ravid et al., "Long-Term Stabilizing Effect of Angiotensin-Converting Enzyme Inhibition on Plasma Creatinine and on Proteinuria in Normotensive Type II Diabetic Patients", Annals of Internal Medicine, Vol. 118, No. 8, pp. 577-581 (1993)	
	Lacourciere Y. et al., "Captopril or conventional therapy in hypertensive type II diabetics," Hypertension, 21: 786-94 (1993)	
	Robert H. Noth et al., "Diabetic Nephropathy: Hemodynamic Basis and Implications for Disease Management", Annals of Internal Medicine, Vol. 110, No. 10, pp. 795-813 (1989)	
	Giancarlo Viberti, "Etiology and Prognostic Significance of Albuminuria in Diabetes", Diabetes Care, Vol. 11, No. 10, pp. 840-845 (1988)	
	Hans-Henrik Parving et al., "Prevalence and causes of albuminuria in non-insulin-dependent diabetic patients", Kidney International, Vol. 41, pp. 758-762 (1992)	
	William F. Keane et al., "Renal Protective Effects of Angiotensin-Converting Enzyme Inhibition", The American Journal of Cardiology, Vol. 65, pp. 491-531 (1990)	
	Susan Savage et al., "Progressive Renal Insufficiency: The Role of Angiotensin Converting Enzyme Inhibitors", Advances in Internal Medicine, Vol. 37, pp. 85-101 (1991)	
	Anthony F. Lever, "Angiotensin II, Angiotensin-Converting Enzyme Inhibitors and Blood Vessel Structure", The American Journal of Medicine, Vol. 92 (Suppl 4B), pp. 35 S-38 S (1992)	
	T.F. Lüscher, "Angiotensin, ACE inhibitors and endothelial control of vasomotor tone", Basic Res Cardiol., Vol. 88 (Suppl 1), pp. 15-24 (1993)	
	Richard Donnelly, "Angiotensin-Converting Enzyme Inhibitors and Insulin Sensitivity: Metabolic Effects in Hypertension, Diabetes and Heart Failure", Journal of Cardiovascular Pharmacology, Vol. 20 (Suppl. 11), pp. S38-S44 (1992)	
	John D. Rutherford et al., "Effects of Captopril on Ischemic Events After Myocardial Infarction: Results of the Survival And Ventricular Enlargement Trial", Circulation, Vol. 90, pp. 1731-1738 (1994)	
	Victor J. Dzau, "Cardiac Renin-Angiotensin System", The American Journal of Medicine, Vol. 84 (Suppl 3A), pp. 22-27 (1988)	
	Victor J. Dzau, "Angiotensin converting enzyme inhibitors and the cardiovascular system", Journal of Hypertension, Vol. 10 (Suppl 3), pp. S3-S10 (1992)	
	SOLVD Investigators, "Effect of enalapril on survival in patients with reduced left ventricular ejection fractions and congestive heart failure", The New England Journal of Medicine, Vol. 325, No. 5, pp. 293-302 (1991)	
	SOLVD Investigators, "Effect of enalapril on mortality and development of heart failure in asymptomatic patients with reduced left ventricular ejection fractions", The New England Journal of Medicine, Vol. 327, No. 10, pp. 685-691 (1992)	

 4/19/06

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

4


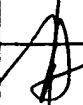
of

6

Complete if Known

Application Number	10/694,001
Filing Date	October 28, 2003
First Named Inventor	Bernward Scholkens
Art Unit	1614
Examiner Name	R. Henley
Attorney Docket Number	02481.1707-01

NON PATENT LITERATURE DOCUMENTS

	K. Fred Gey et al., "Inverse correlation between plasma vitamin E and mortality from ischemic heart disease in cross-cultural epidemiology", Am J Clin Nutr., Vol. 53 (Supp 1), pp. S326-S334 (1991)	
	Shrikant I. Bangdiwala et al., "Studies of Left Ventricular Dysfunction (SOLVD) Registry: Rationale, Design, Methods and Description of Baseline Characteristics", The American Journal of Cardiology, Vol. 70, No. 33, pp. 347-53 (1992)	
	Salim Yusuf et al., "Effect of Angiotensin-Converting Enzyme Inhibitors in Left Ventricular Dysfunction: Results of the Studies of Left Ventricular Dysfunction in the Context of Other Similar Trials", Journal of Cardiovascular Pharmacology, Vol. 22 (Suppl 9), pp. S28-S35 (1993)	
	Nancy J. Brown et al., "Angiotensin-Converting Enzyme Inhibitors", Cardiovascular Drugs, Vol. 97, No. 14, pp. 1411-1420 (1998)	
	Michael Marre et al., "Prevention of diabetic nephropathy with enalapril in normotensive diabetics with microalbuminuria", BMJ, Vol. 297, pp. 1092-1095 (1988)	
	Staffan Björck et al., "Renal protective effect of enalapril in diabetic nephropathy", BMJ, Vol. 304, pp. 339-343 (1992)	
	Allan M. Lefer et al., "Cardioprotective Effects of Enalapril in Acute Myocardial Ischemia", Pharmacology, Vol. 29, pp. 61-69 (1984)	
	Hans-Henrik Parving et al., "Effect of captopril on blood pressure and kidney function in normotensive insulin dependent diabetics with nephropathy", BMJ, Vol. 299, pp. 533-536 (1989)	
	E.R. Mathiesen et al., "Efficacy of captopril in postponing nephropathy in normotensive insulin dependent diabetic patients with microalbuminuria", BMJ, Vol. 303, No. 7, pp. 81-87 (1991)	
	Yoshio Taguma et al., "Effect of Captopril on Heavy Proteinuria in Azotemic Diabetics", The New England Journal of Medicine, Vol. 313, No. 26, pp. 1617-1620 (1985)	
	Marc A. Pfeffer et al., "Survival after an experimental myocardial infarction: beneficial effects of long-term therapy with captopril", Circulation, Vol. 72, No. 2, pp. 406-412 (1985)	
	Robert L. Hall et al., "Captopril Slows the Progression of Chronic Renal Disease in Partially Nephrectomized Rats", Toxicology and Applied Pharmacology, Vol. 80, pp. 517-526 (1985)	
	Staffan Björck et al., "Beneficial effects of angiotensin converting enzyme inhibition on renal function in patients with diabetic nephropathy", BMJ, Vol. 293, pp. 471-774 (1986)	
	Eva Hommel et al., "Effect of captopril on kidney function in insulin-dependent diabetic patients with nephropathy", BMJ, Vol. 293, pp. 467-470 (1986)	
	Hans-Henrik Parving et al., "Protection of kidney function and decrease in albuminuria by captopril in insulin dependent diabetics with nephropathy", BMJ, Vol. 297, pp. 1086-1091 (1988)	
	Jan E. Heeg et al., "Reduction of proteinuria by angiotensin converting enzyme inhibition," Kidney International, Vol. 32, pp. 78-83 (1987)	
	V. J. Dzau, "Clinical implications for therapy: possible cardioprotective effects of ACE inhibition," Br J Clin Pharmac., Vol. 28, pp. 183S-187S (1989)	
	Michel Marre et al., "Converting enzyme inhibition and kidney function in normotensive diabetic patients with persistent microalbuminuria," BMJ, Vol. 294, pp. 1448-1452 (1987)	
	The CONSENSUS Trial Study Group, "Effects of Enalapril on Mortality in Severe Congestive Heart Failure," The New England Journal of Medicine, Vol. 316, No. 23, pp. 1429-1435 (1987)	
	Nancy J. Brown et al., "Selective Stimulation of Tissue-Type Plasminogen Activator (t-PA) In Vivo by Infusion of Bradykinin," Thrombosis and Haemostasis, Vol. 77, No. 3, pp. 522-525 (1997)	
	Tony Hayek et al., "Effect of Angiotensin Converting Enzyme Inhibitors on LDL Lipid Peroxidation and Atherosclerosis Progression in Apo E Deficient Mice," Circulation, Vol. 92, No. 8, p. 1-625 (1995)	
	Stefan Engeli et al., "Co-expression of renin-angiotensin system genes in human adipose tissue", Journal of Hypertension, Vol. 17, No. 4, pp. 555-560 (1999)	

Raymond J. Henley 4/20/06

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

5

of

6

Complete if Known

Application Number	10/694,001
Filing Date	October 28, 2003
First Named Inventor	Bernward Scholkens
Art Unit	1614
Examiner Name	R. Henley
Attorney Docket Number	02481.1707-01

NON PATENT LITERATURE DOCUMENTS

	Agnes Fogo et al., "Importance of angiogenic action of angiotensin II in the glomerular growth of maturing kidneys", <i>Kidney International</i> , Vol. 38, pp. 1068-1074 (1990)	
	Iekuni Ichikawa et al., "Glomerular Actions of Angiotensin II", <i>The American Journal of Medicine</i> , pp. 43-49 (1984)	
	Sharon Anderson et al., "Therapeutic Advantage of Converting Enzyme Inhibitors in Arresting Progressive Renal Disease Associated with Systemic Hypertension in the Rat", <i>Hypertension and Glomerular Injury in Rats</i> , Vol. 77, pp. 1993-2000 (1986)	
	Mordchai Ravid et al., "Long-Term Renoprotective Effect of Angiotensin-Converting Enzyme Inhibition in Non-Insulin-Dependent Diabetes Mellitus", <i>Arch Intern Med.</i> , Vol. 156, pp. 286-289 (1996)	
	The Acute Infarction Ramipril Efficacy (AIRE) Study Investigators, "Effect of ramipril on mortality and morbidity of survivors of acute myocardial infarction with clinical evidence of heart failure", <i>The LANCET</i> , Vol. 342, pp. 821-828 (1993)	
	Paul M. Ridker et al., "Stimulation of Plasminogen Activator Inhibitor <i>In Vivo</i> by Infusion of Angiotensin II - Evidence of a Potential Interaction Between the Renin-Angiotensin System and Fibrinolytic Function", <i>Circulation</i> , Vol. 87, No. 6, pp. 1969-1973 (1993)	
	G.B. John Mancini et al., "Angiotensin-Converting Enzyme Inhibition with Quinapril Improves Endothelial Vasomotor Dysfunction in Patients with Coronary Artery Disease - the TREND (Trial on Reversing Endothelial Dysfunction) Study", <i>Circulation</i> , Vol. 94, No. 3, pp. 258-265 (1996)	
	Piero Ruggenenti et al., "Renal function and requirement for dialysis in chronic nephropathy patients on long-term ramipril: REIN follow-up trial", <i>The LANCET</i> , Vol. 352, pp. 1252-1256 (1998)	
	Rhonda Rowland, "Cardiology mapping new approaches to treatment," <i>cnn.com</i> , providing a date of November 1999	
	The Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (1997)	
	Merck Index, 12 th Ed., pp. 1394-1395 (1996)	
	News Release, "Hope Study Indicates Ramipril Could Save One Million Lives Each Year", distributed by PR Newswire Europe Ltd. on behalf of McMaster University health Sciences, providing a date of May 1999	
	Wolfgang Linz et al., "Long-term ACE Inhibition Doubles Lifespan of Hypertensive Rats," <i>Circulation</i> , Vol. 96, No. 9, pp. 3164-3172 (1997)	
	Basis of Internal Medicine, 4 th Edition, Edited by Chen Haozhu, Peoples Medical Publishing House, pp. 226, 227, 230, 232, 238, 242, and 243 (1996), and partial translation	
	Leslie Papp, "Researchers call off \$11-million heart study," published in the Toronto Star newspaper, p. A5 (1999)	
	Susan Clairmont, "Heart Doc Loses Hope \$11M Research Project Ends Early," Hamilton Spectator newspaper, p. A3, providing a date of May 1999	
	Suzanne Morrison, "Heart Drug Called Major Discovery Ramipril Better Than Aspirin, Fewer Side Effects, Hamilton Spectator newspaper, p. A7, providing a date of May 1999	
	Leslie Papp, "Aborted vitamin E study will be given second look," Toronto Star newspaper, p. A5 (May 1999)	
	Susan Jeffrey, "New HOPE in heart study," Medical Post, vol. 35, No. 20, p. 1 (May 1999)	
	Karen Tu et al., "The striking effect of the Heart Outcomes Prevention Evaluation (HOPE) on ramipril prescribing in Ontario," <i>Canadian Medical Association Journal</i> , Vol. 168, No. 5, pp. 553-557 (2003)	
	Wilbert S. Aronow, "Treatment of Congestive Heart Failure in Older Persons," <i>JAGS</i> , Vol. 45, No. 10, pp. 1252-1258 (1997)	
	Salim Yusuf et al., "Changes in Hypertension Treatment and in Congestive Heart Failure Mortality in the United States," <i>Hypertension</i> , Vol. 13, No. 5, pp. 174-179 (1989)	
	Karl Swedberg et al., "Effects of the early administration of enalapril on mortality in patients with acute myocardial infarction," <i>New England Journal of Medicine</i> , Vol. 327, No. 10, pp. 678-684 (1992)	

R. J. H. 4/20/06

IDS Form PTO/SB/08: Substitute for form 1449A/PTO			Complete if Known		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>			Application Number	10/694,001	
			Filing Date	October 28, 2003	
			First Named Inventor	Bernward Scholkens	
			Art Unit	1614	
			Examiner Name	R. Henley	
Sheet	6	of	6	Attorney Docket Number	02481.1707-01

NON PATENT LITERATURE DOCUMENTS		
		Claude R. Benedict et al., "Comparative Neurohormonal Responses in Patients with Preserved and Impaired Left Ventricular Ejection Fraction: Results of the Studies of Left Ventricular Dysfunction (SOLVD) Registry," JACC, Vol. 22 (4 Supp A), pp. 146A-153A (1993)
		Salim Yusuf, "Overview of the Design and Key Results of the Studies of Left Ventricular Dysfunction (SOLVD)," Heart Failure, Vol. 9, pp. 28-40 (1993)
		F. X. Kleber, "Socioeconomic Aspects of ACE Inhibition in the Secondary Prevention in Cardiovascular Diseases," American Journal of Hypertension, Vol. 7, No. 9, pp. 112S-116S (1994)
		Giancarlo Viberti et al., "Effect of Captopril on Progression to Clinical Proteinuria in Patients With Insulin-Dependent Diabetes Mellitus and Microalbuminuria," JAMA, Vol. 26, No. 4, pp. 275-279 (1994)
		Carl Pepine, "Ongoing Clinical Trials of Angiotensin-Converting Enzyme Inhibitors for Treatment of Coronary Artery Disease in Patients with Preserved Left Ventricular Function," JACC, Vol. 27, No. 5, pp. 1048-1052 (1996)
		Lars H. Lindholm et al., "The Swedish Trial in Old Patients with Hypertension-2 (STOP-Hypertension-2): A Progress Report," Blood Pressure, Vol. 5, pp. 300-304 (1996)
		Mordchai Ravid et al., "Long-term Renoprotective Effect of Angiotensin-converting Enzyme Inhibition in Non-insulin-dependent Diabetes Mellitus," Archives of Internal Medicine, Vol. 156, No. 3, pp. 286-289 (1996)
		Patrizio Tatti, et al, "Outcome Results of the Fosinopril Versus Amlodipine Cardiovascular Events Randomized Trial (FACET) in Patients with Hypertension and NIDDM, Diabetes Care, Vol. 21, No. 4, pp. 597-603 (1998)
		Lionel H. Opie, "Principles of Combination Therapy for Hypertension: What We Learn from the HOT and Other Studies - A Personal Point of View," Cardiovascular Drugs and Therapy, Vol. 12, No. 5, pp. 425-429 (1998)
		Raymond O. Estacio et al., "Antihypertensive Therapy in Type 2 Diabetes: Implications of the Appropriate Blood Pressure Control in Diabetes (ABCD) Trial," American Journal of Cardiology, Vol. 82, No. 9B, pp. 9R-14R (1998)
		Marco Pahor et al., "New Evidence on the Prevention of Cardiovascular Events in Hypertensive Patients with Type 2 Diabetes," Journal of Cardiovascular Pharmacology, Vol. 32 (Supp 2), pp. S18-S23 (1998)
		Claudio Borghi et al., "Evidence-Based Medicine and ACE Inhibition," Journal of Cardiovascular Pharmacology, Vol. 32 (Supp 2), pp. S24-S35 (1998)
		Piero Ruggerenti et al., "Primary prevention of renal failure in diabetic patients: the Bergamo Nephrologic Diabetes Complication Trial," Journal of Hypertension, Vol. 16 (Supp 1), pp. S95-S97 (1998)
		Nancy J. V. Bohannon, "Coronary artery disease and diabetes," Postgraduate Medicine, Vol. 105, No. 2, pp. 66-68, 71-72, and 77-80 (1999)
		Lennart Hansson, "The Hypertension Optimal Treatment study and the importance of lowering blood pressure," Journal of Hypertension, Vol. 17 (Supp. 1), pp. S9-S13 (1999)
		Guidelines Subcommittee, "1999 World Health Organization - International Society of Hypertension Guidelines for the Management of Hypertension," Journal of Hypertension, Vol. 17, No. 2, pp. 151-183 (1999)
		Patent File History of Canadian Patent No. 2,382,387 (NO date available)
		Patent File History of Canadian Patent No. 2,382,549 (date not available)
		Office Action dated November 3, 2005, in US Patent Application No. 09/645,556
		Physician's Desk Reference, 53 rd Ed., pp. 1293-1296 (1999)

Examiner Signature		Date Considered	4/19/06
--------------------	--	-----------------	---------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.